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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/748,495   | 12/30/2003  | Charles R. Roe       | BHCS:1007RCE                  | 8734             |
| 34725  | 7590        | 12/17/2008           |                               |                  |
| CHALKER FLORES, LLP<br>2711 LBJ FRWY<br>Suite 1036<br>DALLAS, TX 75234 |             |                      | EXAMINER<br>GEMBEH, SHIRLEY V |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 1618                          |                  |
|  |             |                      | MAIL DATE                     | DELIVERY MODE    |
|  |             |                      | 12/17/2008                    | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/748,495 | <b>Applicant(s)</b><br>ROE, CHARLES R. |  |
|                              | <b>Examiner</b><br>SHIRLEY V. GEMBEH | <b>Art Unit</b><br>1618                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17, 19-47 and 49-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19-47 and 49-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. The response filed on **10/31/08** has been entered.
2. Applicant's argument filed 10/31/08 has been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 17, 19-47 and 49-57 are pending in this office action.
5. The information disclosure statement (IDS) submitted on 11/19/08 is acknowledged and has been reviewed.
6. Claims 17, 23-25, 34-44 and 46-47 stand rejected under 35 U.S.C. 102(b) as being anticipated by Garzia US 3,697,563 for the reasons made of record in Paper No. 20080918 and as follows.

Applicant argues that Garzia fails to disclose a method of treating a patient in need of a treatment for cardiac disorder by administering to said patient an effective amount of n-heptanoic composition.

In response, the traversal is found not persuasive because, the limitation of providing a patient in need of a treatment is met, (see col. 1, lines 41-49), because

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Garzia disclose treatment of cardiac disorders such as ischemic cardiopathy (i.e., Ischemic cardiomyopathy is a weakness in the muscle of the heart due to inadequate oxygen delivery which therefore meets the limitation of "comprising providing a patient in need of treatment for a cardiac disorder wherein the cardiac disorder is cardiac myopathy). Garzia also discloses that physicians are able to detect symptoms; thereby, meeting the limitation comprising the step of providing a patient in need thereof. It is noted that independent claim 17 recites "administering to said patient an amount of a n-heptanoic acid composition". Therefore, giving the claims it broadest reasonable claim interpretation, the compound of Garzia  $\xi$ (3,4,5- trimethoxybenamido)-heptanoic acid is a n-heptanoic acid composition.

As to the remarks that Garzia disclose that an even carbon molecule is preferred, this is not given any weight because the claims do not recite such a limitation.

Careful consideration is given to the remarks but they are not persuasive for the reasons given above.

7. Claims 17, 19-47 & 49-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia US 3,697,563 in view of Jandacek et al., US 4,753,963 and Jones et al. British Med. J. 1961, 1276-1278 for the reasons made of record in Paper No. 20080918 and as follows.

Applicant argues that the combination of prior art references fails to teach the claim limitations as discussed supra with regards to Garzia. Applicant also argues that "Jandacek does not cure the deficiencies in Garzia but merely teaches nutritional fat

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particularly suitable for enternal and parenteral products". Applicant argues that the mere broad listing of different compounds by Jandacek does not place a seven carbon fatty acid selected from n-heptanoic acid or triheptanoin in possession. Next, Applicant argues that "a prior art reference which contains a broad general disclosure ...will not anticipate". With regards to Jones, Applicant then argues that "Jones teaches that fat-mal-absorption in congestive heart failure leads to steatorrhoe", and therefore the skilled artisan would not come to the conclusion that if fats were not absorbed but excreted in stool, it would be of little benefit to provide a fat supplement or a diet including fat.

In response, see supra for arguments pertaining Garzia. With regards to Jones and the remarks that the reference does not anticipate the claim invention, Applicant should note that this is not a 102 rejection but an obviousness rejection.

With regard to Jandacek, it is noted that Jandacek teaches a formulation comprising triglyceride that overlaps with the triglycerides of instant claim 20 (e.g., triheptanoin). In addition Garzia, Jandacek and Jones need not teach all the claim limitations individually. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicants' assertion that Jones alternatively teaches that fat mal-absorption in congestive heart failure leads to steatorrhea is found not persuasive, because whether

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mal-absorption leads to steatorrhea is immaterial, what is material is whether fat mal-absorption contributes to congestive heart failure. Thus, Applicants' arguments are not persuasive.

8. Claims 53-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Garzia (US 3,697,563) in view of Jandacek et al. (US 4,753,963) and Jones et al. (1961) **as applied to claims 17, 19-47 & 49-52 above**, and further in view of Niezen-Koning (1995) and Bach et al. (1982), for the reasons made of record in Paper No. 20080918 and as follows.

Applicants' only argument is that no prima facie obviousness is established in the combination of the above cited references.

This alleged allegation is found not persuasive because Niezen-Koning teaches disorders that affect the transportation of long chain fatty acid. Niezen-Koning teaches a carnitine-acylcarnitine translocase deficiency, a defect in the transfer of fatty acylcarnitines across the inner mitochondrial membrane in exchange for free carnitine, and Bach et al. teach that fat malabsorption is treated with (medium chain triglyceride) MCT. Bach also teaches the deficiency of such (fat malabsorption) affects the skeletal muscle, and the systemic form of the heart and liver, and that patients who suffer from deficiency of muscular carnitine have been successfully treated with a MCT based diet, thus motivating the skilled artisan to employ the formulation of Jandacek for the treatment of a translocase deficiency, because MCT's are absorbed faster than LCT's

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(long chain fatty acids). See pages 954, clinical uses under fat malabsorption and 956, rt. col. lines 3 from the top.

Thus, it would have been obvious to one of ordinary skill in the art to combine the cited prior art and administer MCTs, which are well absorbed and easily transported to the plasma, in the formulation of Jandacek for treating a translocase deficiency, such as a deficiency of the carnitine system, as previously made of record.

9. The provisional obviousness type double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

Claims 17,19-47 and 49-57 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25-27, 37-40, 42-45 and 47-56 of U.S. Patent No. 10/371,385 for the reasons made of record in Paper No. 20080918. Although the conflicting claims are not identical, they are not patentably distinct from each other.

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10. Claims 17,19-47 and 49-57 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748432, in view of Rice et al., Neurology for the reasons made of record in Paper No. 20080918. Although the conflicting claims are not identical, they are not patentably distinct from each other.

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shirley V Gembeh/  
Examiner, Art Unit 1618  
12/04/08

/Robert C. Hayes/  
Primary Examiner, Art Unit 1649